

REMARKS

Claims 1-13 are pending. Applicant has amended claim 1 to provide greater clarity. Support for the amendment is found at page 8, lines 25-28, page 9, lines 11-15, and page 10, lines 1-5. Accordingly, this amendment does not introduce any new matter.

Rejection Under 35 U.S.C. § 102(b)

Claims 1-13 are rejected under 35 U.S.C. § 102(b) as being anticipated by Fitch et al. Specifically, the Examiner states that the pending claims are drawn to a method of determining the effectiveness of an anti-inflammatory compound in a patient undergoing a procedure involving cardiopulmonary bypass (CPB) and comparing incidence of infarctions with control subjects wherein both groups have a blood level of creatine kinase (as CK-MB) of at least a certain level in ng/ml, and alleges that the claimed methods are not different in practice from the method taught by Fitch et al. The Examiner alleges that if subjects in the study by Fitch reach a level of greater than 50-120 ng/ml at any point during the "cumulative" measurement, then those subjects satisfy the metes and bounds of the claims as presented. The Examiner recommends amending the base claim to positively recite a step of measuring the peak level. Applicant respectfully traverses this rejection.

Fitch et al. teach that a single-chain antibody specific for human C5 is effective against pathological complement activation in patients undergoing CPB and that postoperative myocardial injury can be determined by measuring the cumulative release of CK-MB over 24 hours. In particular, Figure 4 in Fitch et al. shows the measurement of the cumulative release of CK-MB over 24 hours as represented by CK-MB AUC (area under the curve). However, Fitch et al. do not teach measuring the postoperative peak level of CK-MB or suggest any significance of the peak level of CK-MB as opposed to the cumulative level or AUC of CK-MB. Applicant respectfully submits that the peak level and AUC are two distinct pharmacokinetic parameters and a measurement of AUC is different from a measurement of the peak level. Accordingly, Fitch et al. do not teach or suggest measuring the peak level of CK-MB as required by the pending claims.

However, in an effort to expedite prosecution, the Applicant has amended claim 1 to recite "measuring the peak level of CK-MB in the blood by analyzing intra- and post-operative blood draws." Support for this is found at page 9, lines 11-12, where it is stated that measurements were made on "intra- and post-operative blood draws." Thus, the pending claims are patentable over Fitch et al., and reconsideration and withdrawal of this rejection are respectfully requested.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1-13 are rejected under 35 U.S.C. § 112, second paragraph.

The Examiner alleges that claim 1 is ambiguous and unclear as to whether a patient in a larger subject group undergoes a procedure involving cardiopulmonary bypass with the rest of the patients not undergoing the procedure. Applicant respectfully traverses. The claim is intended to cover a subject group in which all of the patients are undergoing a procedure involving cardiopulmonary bypass, wherein the group comprises at least one patient. Applicant has amended claim 1 to recite "a subject group undergoing a procedure involving cardiopulmonary bypass comprising at least one patient." Support for this is found at page 8, lines 25-28.

The Examiner further alleges that claim 1 is ambiguous and unclear as to what occurs when there are no infarctions in one or both groups. The claim is intended to indicate effectiveness of a compound when there is a significant decrease in the incidence of infarctions. Applicant has amended claim 1 to recite "a significant decrease." Support for this is found at page 10, lines 1-5. Therefore, claim 1 as amended is clear and unambiguous.

Accordingly, reconsideration and withdrawal of these rejections are respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant submits that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Please charge any fees or credit any overpayments to our Deposit Account No. 18-1945 from which the undersigned is authorized to draw, under order no. ALXN-P02-059.

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Respectfully submitted,

By ANITA VARMA 54,408
Anita Varma
Registration No.: 43,221
FISH & NEAVE IP GROUP
ROPES & GRAY LLP
One International Place
Boston, Massachusetts 02110-2624
(617) 951-7000
(617) 951-7050 (Fax)
Attorneys/Agents For Applicant

Anita Varma